JS

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA: CRIMINAL NO. 10 - 399

v. : DATE FILED: _____

CHARLOTTE J. LOPACKI : VIOLATIONS:

21 U.S.C. § 331(a), 333(a)(2) & 353(b)(1)

(introduction of misbranded drugs into

interstate commerce – 3 counts)

: Notice of forfeiture

:

:

INFORMATION

COUNTS ONE THROUGH THREE

FILED J.J. 2 1 7019 MICHAEL E. KUNZ. Clerk By Dop. Clerk

THE UNITED STATES ATTORNEY CHARGES THAT:

At all times relevant to this information, that is, from at least July 2004 through September 12, 2005:

- 1. Defendant CHARLOTTE J. LOPACKI was licensed to practice as a pharmacist in the Commonwealth of Pennsylvania and was the owner and operator of a walk-in pharmacy known as Budget Drug and Wellness Center, located at 1137 Bustleton Pike, Feasterville, Pennsylvania, and the owner and operator of an Internet pharmacy known as Budget Drug Rx.
- 2. Budget Drug Rx filled and shipped orders for controlled prescription drugs, primarily weight-loss drugs such as phendimetrazine and phentermine, placed by customers of Internet websites. The websites allowed customers to purchase controlled prescription drugs without a valid prescription. The customers selected the type, quantity and strength of the drugs and completed

online questionnaires. The website operators hired doctors to review the questionnaires and issue prescriptions, and pharmacies, including Budget Drug Rx, to fill the prescriptions and ship them to the customers, who were located throughout the United States. The doctors, who resided in different states than most of the customers, never examined or met any of the Internet customers before issuing the prescriptions.

- 3. Under the Federal Food, Drug, and Cosmetic Act ("FDC A"), 21 U.S.C. §§ 301-397, "prescription drugs" were those drugs, which, because of their toxicity or other potential harmful effects, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or which were required to be administered under the professional supervision of a practitioner licensed by law to administer such drugs as a condition of FDA approving any such drug to be placed on the market. 21 U.S.C. § 353(b)(l)(A) and (B). All controlled substances are prescription drugs. 21 U.S.C. § 829.
- 4. Controlled substances can only be lawfully distributed to individuals with a valid prescription issued by a physician or other authorized health practitioner, except when dispensed directly to a patient by the practitioner (other than a pharmacist). 21 U.S.C. § 829. Section 1306.04 of Title 21 of the Code of Federal Regulations, which governs the issuance of prescriptions for controlled substances, states that every prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." A prescription not meeting this standard is invalid.
 - 5. A prescription for a controlled substance based solely on the customer's responses

to a questionnaire completed over the Internet, without a physical examination, is issued outside the usual course of professional practice, is not for a legitimate medical purpose, and therefore is invalid.

- 6. Phendimetrazine and phentermine are weight loss drugs that are indicated for short-term use and are classified as Schedule III and IV controlled substances, respectively.
- 7. The act of dispensing prescription drugs without the valid prescription of a practitioner licensed by law to administer such drug was an act which caused the drug to become misbranded. Title 21, United States Code, Section 353(b)(1).
- 8. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded is a violation of federal criminal law. Title 21, United States Code, Section 331(a).
- 9. Internet sites known to the United States Attorney sold controlled prescription drugs, primarily weight-loss drugs, to customers who selected the type, quantity and strength of the drugs they wanted and completed online medical questionnaires.
- 10. The operators of these websites recruited and hired physicians to review the customers' online questionnaires and to issue prescriptions based solely upon the customers' responses, without ever seeing or examining the customers, and pharmacies, including Budget Drug Rx, which was owned and operated by defendant CHARLOTTE J. LOPACKI, to fill and ship these invalid prescriptions.
- 11. Defendant CHARLOTTE J. LOPACKI, a pharmacist licensed in the State of Pennsylvania and the operator of Budget Drug Rx, either directly or through her employees, filled these invalid prescriptions and caused the drugs to be shipped to customers in the United States.

12. On or about the dates shown below, in the Eastern District of Pennsylvania and elsewhere, defendant

CHARLOTTE J. LOPACKI

introduced controlled prescription drugs into interstate commerce and delivered controlled prescription drugs for introduction into interstate commerce, which drugs were misbranded because they were introduced and delivered without a valid prescription of a practitioner licensed by law to administer such drug, each drug order that was introduced and delivered constituting a separate count:

Count	Date	Drug	Quantity	Delivered to
1	8/9/2005	phentermine	90	Vicco, KY
2	9/1/2005	phentermine	270	Bloomfield, MO
3	9/8/2005	phendimetrazine	90	Sacramento, CA

In violation of Title 21, United States Code, Sections 353(b)(1), 331(a), and 333(a)(2).

NOTICE OF FORFEITURE

THE UNITED STATES ATTORNEY FURTHER CHARGES THAT:

As a result of the violations of Title 21, United States Code, Sections 353(b)(1),
 331(a), and 333(a)(2), set forth in this information, defendant

CHARLOTTE J. LOPACKI

shall forfeit to the United States of America any quantities of the prescription drugs which were misbranded within the meaning of Title 21, United States Code, Section 353(b)(1), in that the drugs were dispensed without a valid prescription as required by law, in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2), as charged in this information.

- 2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:
 - a. cannot be located upon the exercise of due diligence;
 - b. has been transferred or sold to, or deposited with, a third party;
 - has been placed beyond the jurisdiction of the Court;
 - d. has been substantially diminished in value; or
 - e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to

seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture.

All pursuant to Title 21, United States Code, Sections 334 and 853, and Title 28, United States Code, Section 2461(c).

ZANE DAVID MEMEGER

UNITED STATES ATTORNEY